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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,519	02/20/2004	Philip Stashenko	25669-012 CON DIV	2668

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Ingrid A. Beattie
Mintz, Levin, Cohn,
Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER

HOWARD, ZACHARY C

ART UNIT PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,519	STASHENKO ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 1/19/07 has been entered in full. Claims 4, 5 and 32 are amended. Claims 31 and 33 are canceled (claims 2 and 6-29 were cancelled previously).

Claims 1, 3, 4, 5, 30 and 32 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (7/19/06).

The objection to the specification at pg 2 is *withdrawn* in view of Applicants' amendments to the specification.

The objection to claim 4 is *withdrawn* in view of Applicants' amendments to the claim.

All rejections of claims 31 and 33 are moot in view of Applicants' cancellation of these claims.

The rejection of claim 32 under 35 U.S.C. § 101 at pg 3-4 is *withdrawn* in view of Applicants' amendments to the claim that indicate the claimed cell is "an isolated cell".

The rejection of claims 5 and 32 under 35 U.S.C. § 112, first paragraph at pg 4-9 for failing to provide enablement for the full scope of the claims is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 5 and 32 under 35 U.S.C. § 112, first paragraph at pg 10-12 for failing to comply with the written description requirement is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claim 5 under 35 U.S.C § 112, second paragraph, at pg 12-13 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claim 32 under 35 U.S.C. § 102(a) as anticipated by Li (1995) at pg 14 is *withdrawn* in view of Applicants' amendments to the claim that introduces the

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limitations "[a]n isolated cell" and "wherein said cell is transformed with said vector". Li (1995) does not teach cells with these limitations.

The rejection of claim 5 under 35 U.S.C. § 102(a) as anticipated by Peng (1994) at pg 14-16 is *withdrawn* in view of Applicants' amendments to the claim that remove the recitations of sequences that hybridize to SEQ ID NO: 1.

The rejection of claim 5 under 35 U.S.C. § 102(e) as anticipated by Stashenko, U.S. Patent 5,552,281 at pg 16 is *withdrawn* in view of Applicants' amendments to the claim that remove the recitations of sequences that hybridize to SEQ ID NO: 1.

The rejection of claim 5 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 6,403,304 at pg 17-18 is *withdrawn* in view of Applicants' amendments to the claim that remove the recitations of sequences that hybridize to SEQ ID NO: 1.

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-5, 30 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al, 1996 (January 26th. Biochemical and Biophysical Research Communications. 218: 813-821; cited as reference AR on the 2/20/04 IDS). This rejection was set forth at pg 13-14 of the 7/19/2006 Office Action.

Applicants' arguments (1/19/07) as they pertain to the rejection have been fully considered but are not deemed to be persuasive. In view of Applicants' amendments to the claims, the basis for the rejection is first restated herein. Applicants' arguments are then addressed.

The earliest filing date to which the instant application claims priority is February 22nd, 1996. The reference of Li (published January 26th, 1996) shares two inventors with

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the instant Application but is considered to be invented by others because it has an author that is not included in the instant application.

In Figure 2 (pg 816), Li teaches a polynucleotide sequence of 2640 nucleotides that is identical to instant SEQ ID NO: 1. Further, the sequence taught by Li encodes a polypeptide of 822 amino acids that is identical to instant SEQ ID NO: 2. For these reasons, Li anticipates instant claims 1 and 3-5.

Claim 30 encompasses a polynucleotide of claim 5 operably linked to a regulatory sequence. Li also teaches 57 bases of the 5' untranslated region and ~120 bases of the 3' untranslated region of the proton pump gene (Figure 2, pg 816). These regions meet the definition of "regulatory sequence". Therefore, the teachings of Li also anticipate claim 30.

Li further teaches that the polynucleotide sequence shown in Figure 2 was isolated from a osteoclastoma tumor cell cDNA library. See page 814. The cDNA library was "prepared in pcDNA11 vector" and clones were screened. The clone that was identified as the one comprising the polynucleotide sequence shown in Figure 2 meets the definition of an isolated cell comprising a transformed vector comprising the polynucleotide of instant SEQ ID NO: 1. Therefore, the teachings of Li also anticipate claim 32.

In the response dated 1/19/07, Applicants traverse the rejection and submit that the Li 1996 reference does not describe an invention that was known or used by others before invention by Applicants under 35 U.S.C. § 102(a). Applicants argue that the instant application is based in part on work that was reported in a manuscript that subsequently published as the Li 1996 reference that the Examiner has cited against this application. Applicants submit that Philip Stashenko, one of the named inventors of the instant application and an author of the Li 1996 reference, was the Principal Investigator of the laboratory where the inventions described in the instant Application were invented and that while Wei Chen was an author of the Li 1996 reference, Dr. Chen is not an inventor of the subject matter of the claimed invention. Applicant argues that the criteria for determining the authorship of a scientific publication, such as a journal article, are not identical to the criteria for determining inventorship in a patent

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application, and the fact that a scientific publication names more authors than the inventors listed on a given application does not mean that the publication is "by another". Applicants further argue that the inventions claimed in the instant application were invented before the publication date of the Li 1996 reference and that specific portion of the Li reference correspond to specific sections of the instant specification. Applicants argue that as the polynucleotides described in the Li 1996 reference are the same as the polynucleotides described and claimed in this Application, the inventions claimed in instant application were necessarily invented before the publication date of the Li 1996 reference.

Applicants' arguments have been fully considered but are not found persuasive.

In addition, MPEP 2132.01 states, "A prima facie case is made out under 35 U.S.C. 102(a) if, within 1 year of the filing date, the invention, or an obvious variant thereof, is described in a "printed publication" whose authorship differs in any way from the inventive entity unless it is stated within the publication itself that the publication is describing the applicant's work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)."

In the instant case, the inventive entity of the Li reference is different from the inventive entity of the instant application. There is no statement in the Li reference that the reference is describing the material of the instant application. Therefore, a prima facie case has been made out under 35 U.S.C. 102(a).

MPEP 715.01(c) states, "Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37 CFR 1.131. Alternatively, the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 CFR 1.132 establishing that the article is describing applicant's own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. 102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)." In the instant case, Applicants have not filed an affidavit or declaration under 37 CFR 1.131 or 37 CFR 1.132. Therefore, the rejection under 35 U.S.C. 102(a) is maintained for the reasons set forth above.

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Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER